

Notice of Allowability

Application No.

10/677,988

Applicant(s)

SHEPPECK, JAMES

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to responses filed on 11/09, 2005.
2. ☒ The allowed claim(s) is/are 1-10, 13 and 19-25, now are 1-18.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. ☐ Notice of References Cited (PTO-892) | 5. ☐ Notice of Informal Patent Application (PTO-152) |
| 2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>08/30/04</u> | 7. ☒ Examiner's Amendment/Comment |
| 4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. ☒ Examiner's Statement of Reasons for Allowance |
| | 9. ☐ Other _____ |

DETAILED ACTION

DETAILED ACTION

1. This application claims benefit of the provisional application: 60/416,349 with a filing date 10/04, 2002.
2. Amendment of claims 1, 3-5, and 7, cancellation of claims 14-18, and addition of claims 19-25 in the amendment filed on 09/29, 2005, is acknowledged. No new matter is found.
3. Amendment of claims 1-5, and 7, cancellation of claims 11-12 and 14-18 in the amendment filed on 11/07, 2005, is acknowledged. Claims 1-10, 13, and 19-25 are pending and prosecuted in the case.

Responses to Amendment

4. Since the provisional rejection of claims 1-9 under obviousness-type double patenting over Duan et al. co-pending application No. 10/858,978, see US 2004/0254231 A1, is the only remaining rejection, therefore, the provisional rejection of claims 1-9 under obviousness-type double patenting is withdrawn herein.
5. Since the non-elected invention, i.e., i.e., heteroaryl, heterocycle, oxazole, isoxazole, thiazole, isothiazole, pyridyl, pyrimidinyl, triazole of variable Z^a or Z⁰ of formula (I), has been eliminated, therefore, objection of claims 1-9 is obviated herein.

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the

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changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Jing G. Sun on November 10, 2005. The application has been amended as follows:

In claim 10, line 1, after "treating", delete "an inflammatory disorder", and insert --inflammation--

In claim 13, line 1, after "13.", delete "(Withdrawn)", and insert --(Currently amended)--

In claim 13, page 20, lines 7-12, delete "periodontitis, and solid tumor growth and tumor invasion by second metastases", and insert --and periodontitis--

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

Claims 1-9 and 19-25 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. . Claims 1-9 and 19-25 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 10 and 13 directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 10 and 13 hereby are rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made on April 29, 2005, is hereby withdrawn.

Claims 1-10, 13, and 19-25 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to hydantoin derivatives as inhibitors of matrix metalloproteinases and/or TNF-alpha converting enzyme (TACE). The closest reference is Sheppeck et al. US 6,890,915, discloses hydantoin and related heterocycles as inhibitors of matrix metalloproteinases and/or TNF-alpha converting enzyme (TACE). The difference between Sheppeck et al. and instant claims is that the instant compounds of formula (I) have not been found in Sheppeck et al. Suggestion for modification of above record to obtain the instant claimed compounds/composition and methods of use has not been found. Claims 1-10, 13, and 19-25 are allowed.

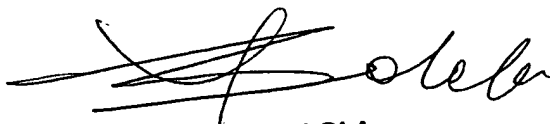
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

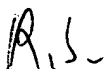
The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TAOFIQ SOLOLA
PRIMARY EXAMINER

Joseph K. McKane
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November 8, 2005